UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,984	03/31/2005	Emadeldin M. Hassan	B4700-597US	6260

26158 7590 03/16/2010

WOMBLE CARLYLE SANDRIDGE & RICE, PLLC
ATTN: PATENT DOCKETING
P.O. BOX 7037
ATLANTA, GA 30357-0037

EXAMINER	
SHTERENGARTS, SAMANTHA L	
ART UNIT	PAPER NUMBER
1626	
MAIL DATE	DELIVERY MODE
03/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,984	HASSAN ET AL.	
	Examiner	Art Unit	
	Samantha L. Shterengarts	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20 and 24-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20 and 24-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 20 and 24-40 are presented for examination.

The action mailed on May 19, 2009 is hereby vacated and replaced with the current action.

In view of the Appeal Brief filed on December 7, 2009, **PROSECUTION IS HEREBY REOPENED**. New grounds of rejection are set forth below.

To avoid abandonment of the application, Appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then Appellant must pay the difference between the increased fees and the amount previously paid.

Claims 20 and 24-40 are pending and under examination.

Applicant's arguments, presented in the Appeal Brief filed December 7, 2009, have been fully considered and are persuasive regarding the application of Hirai et al (U.S. 3,826,666). as prior art. Accordingly, the rejections as set forth against 20 and 24-40 over such references have been withdrawn. Rejections not reiterated from the final Office Action are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31-32 and 34 recites the limitation "alkaline aqueous solution" in lines 1 of each claim respectively. There is insufficient antecedent basis for this limitation in the claim. Specifically, claim 20 recites an "alkaline aqueous solvent," in contrast to the instantly recited "alkaline aqueous solution."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20, 24-25 and 27-40 rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. (WO 01/24780) in view of Ullah et al. (U.S. 6,331,316) and Matthews et al. (U.S. 4,816,259).

Venkateswara et al. discloses an enteric soft capsule shell formed from a gel mass composition comprising a film-forming, water-soluble polymer, including gelatin, an acid-insoluble polymer, including hydroxypropyl methylcellulose phthalate, and an alkaline aqueous solvent (ammonia solution) (pg. 5, lines 21-40; Examples). Venkateswara et al. discloses the acid-insoluble polymer can be 40% by weight of the dried shell (pg. 5, lines 25-27). Given this disclosed weight percent of acid-insoluble polymer therefore, it can be concluded that the remaining polymer is present at ratio of 30:70 (42%).

Venkateswara et al. is silent on the final pH of the gel mass being less than or equal to about 9 pH units and the instantly claimed moisture content.

Ullah et al. (U.S. 6,331,316) teaches raising the pH of the coating suspension provides a more stable composition for an acid labile drug in the core (column 4, lines 39-42).

Matthews et al. teaches it is well known for enteric soft capsule shells to have a moisture content of 8-10% (col. 2, line 18; col. 4, lines 18-20). The capsules taught exhibit an improved mechanical strength and will not crack or undergo substantial deformation during standard large scale capsule manufacturing procedures (column 1, last paragraph).

It would have been prima facie obvious to one of ordinary skill in the art to increase the pH of the enteric soft capsule taught by Venkateswara et al. One would have been motivated to do so because Ullah et al. teaches that an increased pH provides a more stable composition for acid labile drugs which may be present the core. Further, one would have been motivated to modify the moisture content to be

between 8-10% in order to ensure the integrity of the enteric soft capsules given that enteric soft capsules are known to crack or undergo substantial deformation during manufacturing per Matthews et al.

With respect to claims, 20, 39 and 40, the percentage of specific components present in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results form the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Furthermore, with regard to claims 20 and 35, the modification of the optimal pH of the claimed enteric soft capsule would also have been a matter well within the purview of the skilled artisan. Such a determination would also have been made in accordance with a variety of factors, such as modifying the pharmaceutical carriers used to formulate the dosage form to optimize palatability of the dosage form and to maximize tolerability of the composition. In addition, the skilled artisan would also have been motivated to optimize the pH of the solution in order to maintain the active pharmaceutical ingredients in their desired salt form without any degradation of the active ingredients that may occur due to a change in pH.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. (WO 01/24780) in view of Ullah et al. (U.S. 6,331,316) and Matthews et al. (U.S. 4,816,259) as applied to claims 20, 24-25 and 27-40 above, and further in view of Shank et al. (U.S. 4,500,453).

The combination of Venkateswara et al. (WO 01/24780) in view of Ullah et al. (U.S. 6,331,316) and Matthews et al. (U.S. 4,816,259) is set forth *supra*. The combination is silent on the use of gelatin extracted from animal bones or skins which has 100 to about 250 blooms.

Shank et al. teaches it is well known in the art that gelatin is used from animal bones and further gelatin obtained from animals contain lower molecular weight fractions. Further, Shank teaches that enteric capsules which are made with gelatin have about 100 to about 250 blooms (columns 1, lines 22-26 and lines 67 to bridging column 2, line 21).

It would have been prima facie obvious to one ordinary skill in the art to utilize 100-250 blooms because Shank et al. teaches that enteric capsules are known to contain 100-250 blooms when using gelatin from animal bones.

Claims 20, 24-25 and 27-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. (WO 01/24780) in view of Ullah et al. (U.S. 2001/0051188) and Matthews et al. (U.S. 4,816,259).

Venkateswara et al. discloses an enteric soft capsule shell formed from a gel mass composition comprising a film-forming, water-soluble polymer, including gelatin, an acid-insoluble polymer, including hydroxypropyl methylcellulose phthalate, and an alkaline aqueous solvent such as ammonia solution (pg. 5, lines 21-40; Examples). Further, the addition of plasticizers, preservatives, colourants, opacifiers and flavours can be included in the gel mass (page 5, lines 29-31). Venkateswara et al. discloses the acid-insoluble polymer can be 40% by weight of the dried shell. Given this disclosed weight percent of acid-insoluble polymer therefore, it can be concluded that the remaining polymer is present at ratio of 30:70 (42%).

Venkateswara et al. is silent on the final pH of the gel mass being less than or equal to about 9 pH units and the instantly claimed moisture content.

Ullah et al. (U.S. 2001/0051188) teaches when using an acidic enteric coating polymer, the pH of said enteric coating polymer is raised by using a suitable alkalizing agent such as

sodium hydroxide. The pH of the enteric coating polymer is raised to a point which is below the pH wherein the enteric integrity of the polymer could be lost. This partial acid neutralization provides a more stable composition for the acid labile drug in the core (paragraph [0027]).

Matthews et al. teaches enteric soft capsule shells having a moisture content of 8-10% (col. 2, line 18; col. 4, lines 18-20). The capsules taught exhibit an improved mechanical strength and will not crack or undergo substantial deformation during standard large scale capsule manufacturing procedures (column 1, last paragraph).

It would have been prima facie obvious to one of ordinary skill in the art to increase the pH of the enteric soft capsule taught by Venkateswara et al. One would have been motivated to do so because Ullah et al. teaches that an increased pH provides a more stable composition for acid labile drugs which may be present the core. Further, one would have been motivated to modify the moisture content to be between 8-10% in order to ensure the integrity of the enteric soft capsules given that enteric soft capsules are known to crack or undergo substantial deformation during manufacturing per Matthews et al.

With respect to claims, 20, 39 and 40, the percentage of specific components present in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results form the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Furthermore, with regard to claims 20 and 35, the modification of the optimal pH of the claimed enteric soft capsule would also have been a matter well within the purview of the skilled artisan. Such a determination would also have been made in accordance with a variety of factors, such as modifying the pharmaceutical carriers used to formulate the dosage form to optimize palatability of the dosage form and to maximize tolerability of the composition. In addition, the skilled artisan would also have been

motivated to optimize the pH of the solution in order to maintain the active pharmaceutical ingredients in their desired salt form without any degradation of the active ingredients that may occur due to a change in pH.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. (WO 01/24780) in view of Ullah et al. (U.S. 2001/0051188) and Matthews et al. (U.S. 4,816,259) as applied to claims 20, 24-25 and 27-40 above, and further in view of Shank et al. (U.S. 4,500,453).

The combination of Venkateswara et al. (WO 01/24780) in view of Ullah et al. (U.S. 2001/0051188) and Matthews et al. (U.S. 4,816,259) is set forth *supra*. The combination is silent on the use of gelatin extracted from animal bones or skins which has 100 to about 250 blooms.

Shank et al. teaches it is well known in the art that gelatin is used from animal bones and further gelatin obtained from animals contain lower molecular weight fractions. Further, Shank teaches that enteric capsules which are made with gelatin have about 100 to about 250 blooms (columns 1, lines 22-26 and lines 67 to bridging column 2, line 21).

It would have been prima facie obvious to one ordinary skill in the art to utilize 100-250 blooms because Shank et al. teaches that enteric capsules are known to contain 100-250 blooms when using gelatin from animal bones.

Claims 20, 24-25 and 27-40 are rejected under 35 U.S.C. 103(a) as being unpatentable Okajima et al. (U.S. 4,138,013) in view of Ullah et al. (U.S. 2001/0051188) and Matthews et al. (U.S. 4,816,259).

Okijama et al. teaches a gel mass composition comprising a film-forming, water-soluble polymer (gelatin or hydroxypropyl methylcellulose), an acid-insoluble polymer (cellulose acetate phthalate or hydroxypropyl methylcellulose phthalate), an alkaline aqueous solvent (dilute aqueous solution of ammonium hydroxide), and optionally a plasticizer (PEG), and optionally, a coloring agent (col. 3, lines 54-64; col.4, lines 31-38). Okajima et al. illustrates in Example 2 the ratio of acid-insoluble polymer to film-forming polymer being 50:50.

Okijama et al. is silent on the final pH of the gel mass being less than or equal to about 9 pH units and the instantly claimed moisture content.

Ullah et al. (U.S. 2001/0051188) teaches when using an acidic enteric coating polymer, the pH of said enteric coating polymer is raised by using a suitable alkalizing agent such as sodium hydroxide. The pH of the enteric coating polymer is raised to a point which is below the pH wherein the enteric integrity of the polymer could be lost. This partial acid neutralization provides a more stable composition for the acid labile drug in the core (paragraph [0027]).

Matthews et al. teaches enteric soft capsule shells having a moisture content of 8-10% (col. 2, line 18; col. 4, lines 18-20). The capsules taught exhibit an improved mechanical strength and will not crack or undergo substantial deformation during standard large scale capsule manufacturing procedures (column 1, last paragraph).

It would have been prima facie obvious to one of ordinary skill in the art to increase the pH of the enteric soft capsule taught by Venkateswara et al. One would have been motivated to do so because Ullah et al. teaches that an increased pH provides a more stable composition for acid labile drugs which may be present the core. Further, one would have been motivated to modify the moisture content to be between 8-10% in order to ensure the integrity of the enteric soft capsules given that enteric soft capsules are known to crack or undergo substantial deformation during manufacturing per Matthews et al.

With respect to claims, 20, 39 and 40, the percentage of specific components present in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results form the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Furthermore, with regard to claims 20 and 35, the modification of the optimal pH of the claimed enteric soft capsule would also have been a matter well within the purview of the skilled artisan. Such a determination would also have been made in accordance with a variety of factors, such as modifying the pharmaceutical carriers used to formulate the dosage form to optimize palatability of the dosage form and to maximize tolerability of the composition. In addition, the skilled artisan would also have been motivated to optimize the pH of the solution in order to maintain the active pharmaceutical ingredients in their desired salt form without any degradation of the active ingredients that may occur due to a change in pH.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okajima et al. (U.S. 4,138,013) in view of Ullah et al. (U.S. 2001/0051188) and Matthews et al. (U.S. 4,816,259) as applied to claims 20, 24-25 and 27-40 above, and further in view of Shank et al. (U.S. 4,500,453).

The combination of Okajima et al. (U.S. 4,138,013) in view of Ullah et al. (U.S. 2001/0051188) and Matthews et al. (U.S. 4,816,259) is set forth *supra*. The combination is silent on the use of gelatin extracted from animal bones or skins which has 100 to about 250 blooms.

Shank et al. teaches it is well known in the art that gelatin is used from animal bones and further gelatin obtained from animals contain lower molecular weight fractions. Further, Shank teaches that

enteric capsules which are made with gelatin have about 100 to about 250 blooms (columns 1, lines 22-26 and lines 67 to bridging column 2, line 21).

It would have been prima facie obvious to one ordinary skill in the art to utilize 100-250 blooms because Shank et al. teaches that enteric capsules are known to contain 100-250 blooms when using gelatin from animal bones.

Claims 20, 24-25 and 27-40 rejected under 35 U.S.C. 103(a) as being unpatentable over Okajima et al. (U.S. 4,138,013) in view of Ullah et al. (U.S. 6,331,316) and Matthews et al. (U.S. 4,816,259).

Okijama et al. teaches a gel mass composition comprising a film-forming, water-soluble polymer (gelatin or hydroxypropyl methylcellulose), an acid-insoluble polymer (cellulose acetate phthalate or hydroxypropyl methylcellulose phthalate), an alkaline aqueous solvent (dilute aqueous solution of ammonium hydroxide), and optionally a plasticizer (PEG), and optionally, a coloring agent (col. 3, lines 54-64; col.4, lines 31-38). Okajima et al. illustrates in Example 2 the ratio of acid-insoluble polymer to film-forming polymer being 50:50.

Okijama et al. is silent on the final pH of the gel mass being less than or equal to about 9 pH units and the instantly claimed moisture content.

Ullah et al. (U.S. 6,331,316) teaches raising the pH of the coating suspension provides a more stable composition for an acid labile drug in the core (column 4, lines 39-42).

Matthews et al. teaches it is well known for enteric soft capsule shells to have a moisture content of 8-10% (col. 2, line 18; col. 4, lines 18-20). The capsules taught exhibit an improved

mechanical strength and will not crack or undergo substantial deformation during standard large scale capsule manufacturing procedures (column 1, last paragraph).

It would have been prima facie obvious to one of ordinary skill in the art to increase the pH of the enteric soft capsule taught by Venkateswara et al. One would have been motivated to do so because Ullah et al. teaches that an increased pH provides a more stable composition for acid labile drugs which may be present the core. Further, one would have been motivated to modify the moisture content to be between 8-10% in order to ensure the integrity of the enteric soft capsules given that enteric soft capsules are known to crack or undergo substantial deformation during manufacturing per Matthews et al.

With respect to claims, 20, 39 and 40, the percentage of specific components present in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results form the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Furthermore, with regard to claims 20 and 35, the modification of the optimal pH of the claimed enteric soft capsule would also have been a matter well within the purview of the skilled artisan. Such a determination would also have been made in accordance with a variety of factors, such as modifying the pharmaceutical carriers used to formulate the dosage form to optimize palatability of the dosage form and to maximize tolerability of the composition. In addition, the skilled artisan would also have been motivated to optimize the pH of the solution in order to maintain the active pharmaceutical ingredients in their desired salt form without any degradation of the active ingredients that may occur due to a change in pH.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okajima et al. (U.S. 4,138,013) in view of Ullah et al. (U.S. 6,331,316) and Matthews et al. (U.S. 4,816,259) as applied to claims 20, 24-25 and 27-40 above, and further in view of Shank et al. (U.S. 4,500,453).

The combination of Okajima et al. (U.S. 4,138,013) in view of Ullah et al. (U.S. 6,331,316) and Matthews et al. (U.S. 4,816,259) is set forth *supra*. The combination is silent on the use of gelatin extracted from animal bones or skins which has 100 to about 250 blooms.

Shank et al. teaches it is well known in the art that gelatin is used from animal bones and further gelatin obtained from animals contain lower molecular weight fractions. Further, Shank teaches that enteric capsules which are made with gelatin have about 100 to about 250 blooms (columns 1, lines 22-26 and lines 67 to bridging column 2, line 21).

It would have been prima facie obvious to one ordinary skill in the art to utilize 100-250 blooms because Shank et al. teaches that enteric capsules are known to contain 100-250 blooms when using gelatin from animal bones.

Response to Applicant's Remarks

It should be noted that the arguments addressed herein are directed to the references that remain in the rejections.

Applicant alleges that the Examiner has respectively [sic] misrepresented the disclosure of Venkateswara et al. Applicant alleges that the passage does not teach a ratio of acid-insoluble polymer to film-forming polymer and further the weight percentage given is that of the enteric polymer in the dried shell. Applicant alleges that nothing regarding a ratio of acid-insoluble polymer to film-forming polymer is taught and the Examiners assumption is wholly unsupported. Applicant alleges that Venkateswara does not demonstrate a ratio of enteric polymer to gelatin which exceeds 10:30 compared to 30:70 which is the lowest end of the ratio range claimed by the Appellants. Further, Applicant alleges that the

Examiner conceeds that the ratio is not taught. Finally, Applicant alleges that the ratio of enteric polymer to film-forming polymer is critical under the alkaline formulation conditions.

Applicant, repeatedly, states that Venkateswara does not teach the claimed ratio of acid insoluble polymer to film forming polymer. Though Applicant states in paragraph 1 of page 7 in the response filed on 12/7/2009 that allegedly Venkateswara does not teach or suggest a ratio, in paragraph 3 of the same page Applicant seems to concede that Venkateswara in fact does teach a ratio that does not exceed a ratio of 10:30. Applicant is directed to the breadth of their own claim. Claim 20 recites "*about* 30:70 to *about* 45:55 by weight" (emphasis added). Where close prior art exists (such as, in this case, Venkateswara et al. and Okijama et al.), the burden is on Applicant to establish that the term "about" as used in the instant claims is sufficiently clear to avoid such art. In the instant case, Applicant has failed to provide a definition of the term "about" in the instant specification, such as there is no indication or hint as to what amount of variation above or below the recited ratio would constitute infringement of the instant calims. There is nothing in the specification or prosecution history that provides any indication as to what amount of variation is tolerated by the term "about." Absent such information, and further in view of the what is actually disclosed in Venkateswara et al. and Okijama et al., the teachings of Venkateswara et al. and Okijama et al., are understood to meet the instantly claimed ratio. Arguendo the above, the percentage of specific components present in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results form the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. With regard to Applicant's allegations that the ratio is critical under alkaline conditions, this is not found persuasive. Applicant has not guided the Examiner has to *how or why* the ratio is critical. A review of the disclosure does not distinguish from the prior art or provide support. If

applicant intends to rely on unexpected or unforeseen results, attention is invited to MPEP 716. Absent clear, convincing side-by-side data demonstrating unobviousness vis-à-vis the prior art commensurate with the scope of protection sought, the claims are considered prima facie obvious.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha L. Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/
Examiner, Art Unit 1626

/Kamal A Saeed/
Primary Examiner, Art Unit 1626